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|--------------------|-------------|-----------------------|------------------|
| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 08/482,283         | 06/07/95    | THOMPSON              | R 04189.0083-0   |
|                    |             | EXAMINER              |                  |

HM22/0203

SERIAL NUMBER PAPER NUMBER

25

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1646  
DATE MAILED:

02/03/00

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 4/28/99, 7/6/99, 9/17/99, 11/24/99

- This action is FINAL.  
 Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- Claim(s) 1, 17-25, 37-40 is/are pending in the application.  
Of the above, claim(s) 1, 17-21 is/are withdrawn from consideration.  
 Claim(s) \_\_\_\_\_ is/are allowed.  
 Claim(s) 22-25, 37-40 is/are rejected.  
 Claim(s) \_\_\_\_\_ is/are objected to.  
 Claim(s) 1, 17-25, 37-40 were subject to restriction or election requirement.

#### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
 The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
 The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.  
 The specification is objected to by the Examiner.  
 The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
 All  Some\*  None of the CERTIFIED copies of the priority documents have been received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- Notice of Reference Cited, PTO-892  
 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
 Interview Summary, PTO-413  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  
 Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

**Part III: Detailed Office Action**

**Notice:** Effective February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1646.

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The rejection of claims 22-23 under 35 U.S.C. 101 is withdrawn in view of applicants amendments.

The Examiner notes the amendment of the priority claim in this application. Accordingly, the previous rejections of Claims 22-25 under 35 U.S.C. 102(a) as being anticipated by Hannum et al.

10 (U) and under 35 U.S.C. 102(a) as being anticipated by Eisenberg et al. (V) are withdrawn.

**Formal Matters:**

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

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***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: In Figure 6 and Figure 7, the chromatographic peaks are given number 1-18 and 1-7, respectively, but these reference numbers 20 are not mentioned in the description. Correction is required.

*New Matter?* [ There is no description of Figures 20-64, added by amendment in paper #10, in the specification, particularly in the Brief Description of the Drawings. Correction is required.

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The drawings are objected to because in Figure 4A, the text is upside down. Correction is required.

Figures 4, 13, 15, 25, 27-30, 40, 58, 63, and 64 of the instant application are presented on multiple separate panels. 37 C.F.R. § 1.84 (u)(1) states that when partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. The panels of Figures 29, 40, and 58, must 5 be identified by the same number followed by a capital letter. The two panels labeled Figures 29-1 and 29-2, should be renumbered 29A and 29B. Also, for example, the three sheets of "Figure 40" should be renumbered "Figures 40A, 40B, and 40C". Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84 (u)(1), Applicant is required to change the Brief Description of the Drawings and the rest of the specification accordingly 10 (see p. 42, line 20; p. 17, line 8; p. 18, line 17; and p. 18, line 24). If, for example, Figure 4 is divided into Figures 4A and 4B, then the Brief Description and all references to this figure in the specification must refer to Figures 4A and/or 4B. While all drawings except 29, 40, and 58 are correctly numbered, e.g., Figure 4A, Figure 4B, the description of the drawings does not correspond.

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*Oath/Declaration*

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

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The oath or declaration is defective because:

Non-initialed alterations have been made to the oath or declaration. See 37 CFR 1.52(c) and 1.57).

The Residence and Country of Citizenship of inventor R.C. Thompson have been altered without initialing.

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*Double Patenting Rejections:*

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy

Serial Number 08/482283

Art Unit 1646

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reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 22 remains rejected under the judicially created doctrine of double patenting over claim 1 in view of 4 of prior U.S. Patent No. 5,075,222, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent for reasons cited in the previous Office Action, mailed 1/30/98 , at page(s) 4.

Applicants intent to file a terminal disclaimer to overcome this rejection is noted.

Claims 23-25 remain rejected under the judicially created doctrine of double patenting over claims 11 and 17 of U. S. Patent No. 5, 075,222, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent for reasons cited in the previous Office Action, mailed 1/30/98 , at page(s) 4-5.

Applicants intent to file a terminal disclaimer to overcome this rejection is noted.

Claims 24 and 25 remain rejected under the judicially created doctrine of double patenting over claim 1 of U. S. Patent No. 5,453, 490 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent for reasons cited in the previous Office Action, mailed 1/30/98 , at page(s) 5-6.

Applicants intent to file a terminal disclaimer to overcome this rejection is noted.

**Objections and Rejections under 35 U.S.C. §112:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

5       The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10      All claims which recite "70% homologous" are indefinite as the metes and bounds of such cannot be determined without disclosure as to how homology is to be calculated. The determination of percentage identity or homology is not an absolute, but is dependent upon the algorithm being used, and the way in which that algorithm is applied. Parameters which must be specified in determining identity of two nucleic acids include allowance for gaps and gap penalty, and allowance 15 for substitutions and the penalty for such. Without knowing what algorithm is being used to calculate identity, and what the settings for such parameters are, one cannot determine the metes and bounds of all sequences which would meet the limitation of being "x% identical" to the recited sequence. The situation is even more indefinite when, as in the instant case, the word "homology" is used; homology is not synonymous with identity, but rather is a term that is used to indicate evolutionary relatedness 20 of sequences between species. It is a qualitative, rather than a quantitative term. Therefore, the use of the term "homologous" as applied to a claimed sequence is indefinite.

25      Additionally, claim 23 is indefinite as amended because it does not clearly set forth that the recombinant cell has been transformed or transfected with an IL-1*i*- encoding nucleic acid. The claim as written reads on a cell which naturally expresses such a protein and which has been transformed or transfected with *any* nucleic acid. It is suggested that replacement of "DNA molecule" with "recombinant vector" would be remedial of this point.

Serial Number 08/482283

Art Unit 1646

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**Advisory Information:**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 8:00 A.M. to 4:30 P.M.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Lila Feisee, can be reached at (703)308-2731.

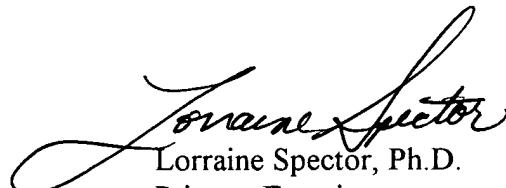
10 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

15 Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

20 Official papers filed by fax should be directed to (703) 305-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Please advise the Examiner at the telephone number above when an informal fax is being transmitted.

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Lorraine Spector  
Primary Examiner

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10/21/98